

# PATENT COOPERATION TREATY

From the  
INTERNATIONAL SEARCHING AUTHORITY

To:  
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# PCT

## WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY

(PCT Rule 43bis.1)

Applicant's or agent's file reference <b>58086-240938</b>		Date of mailing (day/month/year) <b>29 OCT 2007</b>
<b>FOR FURTHER ACTION</b> See paragraph 2 below		
International application No. <b>PCT/US07/05073</b>	International filing date (day/month/year) <b>27 February 2007 (27.02.2007)</b>	Priority date (day/month/year) <b>27 February 2006 (27.02.2006)</b>
International Patent Classification (IPC) or both national classification and IPC <b>IPC: A61K 31/56( 2006.01);C07J 9/00( 2006.01)</b> <b>USPC: 514/182;552/544,552,555</b>		
Applicant <b>REGENTS OF THE UNIVERSITY OF CALIFORNIA</b>		

1. This opinion contains indications relating to the following items:

- |                                     |              |  |
|-------------------------------------|--------------|--|
| <input checked="" type="checkbox"/> | Box No. I    | Basis of the opinion   |
| <input type="checkbox"/>            | Box No. II   | Priority   |
| <input checked="" type="checkbox"/> | Box No. III  | Non-establishment of opinion with regard to novelty, inventive step and industrial applicability   |
| <input type="checkbox"/>            | Box No. IV   | Lack of unity of invention   |
| <input checked="" type="checkbox"/> | Box No. V    | Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement |
| <input type="checkbox"/>            | Box No. VI   | Certain documents cited  |
| <input type="checkbox"/>            | Box No. VII  | Certain defects in the international application   |
| <input checked="" type="checkbox"/> | Box No. VIII | Certain observations on the international application  |

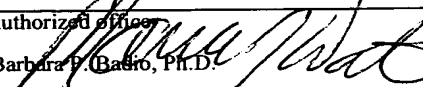
### 2. FURTHER ACTION

If a demand for international preliminary examination is made, this opinion will be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA") except that this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notified the International Bureau under Rule 66.1bis(b) that written opinions of this International Searching Authority will not be so considered.

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of 3 months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.

For further options, see Form PCT/ISA/220.

3. For further details, see notes to Form PCT/ISA/220.

Name and mailing address of the ISA/ US Mail Stop PCT, Attn: ISA/US Commissioner for Patents P.O. Box 1450 Alexandria, Virginia 22313-1450 Facsimile No. (571) 273-3201	Date of completion of this opinion <b>18 October 2007 (18.10.2007)</b>	Authorized officer  Barbara P. Baistro, Ph.D. Telephone No. 571-272-1600
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WRITTEN OPINION OF THE  
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International application No.

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Box No. I Basis of this opinion

1. With regard to the **language**, this opinion has been established on the basis of:

- ☒ the international application in the language in which it was filed  
☐ a translation of the international application into \_\_\_\_\_, which is the language of a translation furnished for the purposes of international search (Rules 12.3(a) and 23.1(b)).

2. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application and necessary to the claimed invention, this opinion has been established on the basis of:

a. type of material

- ☐ a sequence listing  
☐ table(s) related to the sequence listing

b. format of material

- ☐ on paper  
☐ in electronic form

c. time of filing/furnishing

- ☐ contained in the international application as filed.  
☐ filed together with the international application in electronic form.  
☐ furnished subsequently to this Authority for the purposes of search.

3. ☐ In addition, in the case that more than one version or copy of a sequence listing and/or table(s) relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.

4. Additional comments:

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**Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability**

The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non-obvious), or to be industrially applicable have not been examined in respect of:

☐ the entire international application

☒ claims Nos. Claim 30

because:

☐ the said international application, or the said claim Nos. \_\_\_\_\_ relate to the following subject matter which does not require an international search (*specify*):

☒ the description, claims or drawings (*indicate particular elements below*) or said claims Nos. 30 are so unclear that no meaningful opinion could be formed (*specify*):

Claim 30 is an improper multiple dependent claim under PCT Rule 6.4(a).

☐ the claims, or said claims Nos. \_\_\_\_\_ are so inadequately supported by the description that no meaningful opinion could be formed (*specify*):

☐ no international search report has been established for said claims Nos. \_\_\_\_\_

☐ a meaningful opinion could not be formed without the sequence listing; the applicant did not, within the prescribed time limit:

☐ furnish a sequence listing on paper complying with the standard provided for in Annex C of the Administrative Instructions, and such listing was not available to the International Searching Authority in a form and manner acceptable to it.

☐ furnish a sequence listing in electronic form complying with the standard provided for in Annex C of the Administrative Instructions, and such listing was not available to the International Searching Authority in a form and manner acceptable to it.

☐ pay the required late furnishing fee for the furnishing of a sequence listing in response to an invitation under Rules 13*ter*.1(a) or (b).

☐ a meaningful opinion could not be formed without the tables related to the sequence listings; the applicant did not, within the prescribed time limit, furnish such tables in electronic form complying with the technical requirements provided for in Annex C-bis of the Administrative Instructions, and such tables were not available to the International Searching Authority in a form and manner acceptable to it.

☐ the tables related to the nucleotide and/or amino acid sequence listing, if in electronic form only, do not comply with the technical requirements provided for in Annex C-bis of the Administrative Instructions.

☐ See Supplemental Box for further details.

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**Box No. V Reasoned statement under Rule 43 bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement**

**1. Statement**

Novelty (N)	Claims <u>2-5,9,10,13-18,23-27,29,31-33 and 35-57</u>	YES
	Claims <u>1,6-8,11,12,19-22,28 and 34</u>	NO
Inventive step (IS)	Claims <u>2-5,9,10,13-18,23-27,29,31-33 and 35-57</u>	YES
	Claims <u>1,6-8,11,12,19-22,28 and 34</u>	NO
Industrial applicability (IA)	Claims <u>1-29 and 31-57</u>	YES
	Claims <u>NONE</u>	NO

**2. Citations and explanations:**

Claims 1,6-8,11,19, 20-22, 28 and 34 meet novelty under PCT Article 33(2) as being anticipated by Nagano et al. (J. Chem. Research, 1977).

Nagano et al. teaches the cytotoxic effect of several hydroxylated sterols including cholesta-5,24-diene-3,22-diol and 24-norchol-5-ene-3,22-diol (see the entire article, especially page 2528, compounds 53 and 83; page 2536, compound 26). The compounds and compositions taught by the reference are encompassed by the instant claims.

Claims 1, 11 and 12 meet novelty under PCT Article 33(2) as being anticipated by Makino et al. (J. Org. Chem., 1978).

Makino et al. teaches 20-ethyl-5-pregnene-3 $\beta$ ,20-diol (see the entire article, especially page 278, figure 6). The compound and composition taught by the reference are encompassed by the instant claims.

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**Box No. VIII Certain observations on the international application**

The following observations on the clarity of the claims, description, and drawings or on the questions whether the claims are fully supported by the description, are made:

Claims 28, 29, 31-33 and 35-56 are objected to under PCT Rule 66.2(a)(v) as lacking clarity under PCT Article 6 because claims 28, 29, 31-33 and 35-56 are indefinite for the following reason(s): The instant claims recite do not defined what is meant by Oxy 3, Oxy 4, Oxy 7, etc.